K123662

Premarket Notification 510(k)
JustRight Surgical™ Vessel Sealing System
November 26, 2012

MAY 2 2 2013

510(K) SUMMARY

Submitter Information

Submitter's Name: JustRight Surgical LLC
Address: 6235 Gunpark Drive #G
Boulder, CO 80301
Telephone: 720-287-7130
Fax: 720-287-7130

Contact Person: Michele Lucey
Telephone: 603-748-1374

Date Prepared: November 26, 2012

Device Trade Name: JustRight Surgical™ Vessel Sealing System

Classification: Class II

Product Code(s): GEI

Regulation Number(s): 878.4400

Predicate Devices: Valleylab Ligasure™ Vessel Sealing System, K981916 and K070162

Intended Use:
The JustRight Surgical™ Vessel Sealing System is intended for use in open and laparoscopic general surgical procedures to seal blood vessels and vascular bundles up to and including 5 mm in diameter wherever vessel ligation is required.

Device Description/Technological Characteristics:
The JustRight Surgical™ Vessel Sealing System consists of the JustRight™ Generator and a JustRight™ Sealer. The JustRight™ Generator is designed to provide low power bipolar RF energy for vessel-sealing applications. The JustRight™ Generator is for use only with JustRight Sealer instruments. The Sealer is a hand held ring handle design with either a 10 cm or a 20 cm shaft length that is compatible with a 3mm (ID) cannula. The JustRight™ Sealer attaches to the generator via a 10' cord.

Performance Data:
Bench testing of the JustRight Surgical™ Vessel Sealing System was performed to evaluate device function and durability. Electrical safety and Electromagnetic

Compatibility testing was conducted in accordance with IEC 60601-1-1, IEC 60601-1-2, and IEC 60601-2-2.

Biocompatibilty testing was conducted in accordance with ISO 10993.

Animal testing of the JustRight Surgical™ Vessel Sealing System conducted, confirmed device performance to be equivalent to the predicate device.

Substantial Equivalence:
JustRight Surgical™ Vessel Sealing System and the Valleylab Ligasure™ Vessel Sealing System have the same intended use and similar indications, technological characteristics, and principals of operation. Thus, the JustRight Surgical™ Vessel Sealing System is substantially equivalent to the Valleylab Ligasure™ Vessel Sealing System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

JustRight Surgical
% Ms. Michele Lucey
Lakeshore Medical Device Consulting, LLC
128 Blye Hill Landing
Newbury, NH 03255

May 22, 2013

Re: K123662
Trade/Device Name: Justright Surgical™ Vessel Sealing System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting & Coagulation and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 11, 2013
Received: April 23, 2013

Dear Ms. Lucey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification 510(k)
JustRight Surgical™ Vessel Sealing System
November 26, 2012

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: JustRight Surgical™ Vessel Sealing System

Indications for Use:

The JustRight Surgical™ Vessel Sealing System is intended for use in open and laparoscopic general surgical procedures to seal blood vessels and vascular bundles up to and including 5 mm in diameter wherever vessel ligation is required.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S

_____ For

(Division Sign-Off)

Division of Surgical Devices

510(k) Number K123662